

**Statement before the General Law Committee
Tuesday, March 8, 2016**

SB 313 AN ACT CONCERNING BIOLOGICAL PRODUCTS.

My name is Margherita Giuliano and I am both a pharmacist and the Executive Vice President of the Connecticut Pharmacists Association, a professional organization representing 1,000 pharmacists in the State. I am submitting testimony to address **SB 313 An Act Concerning Biological Products**.

The CPA supports legislation that will allow for the interchangeability of a biologic drug based on recommendation from the Food and Drug Administration (FDA). The FDA currently determines what is considered a safe drug substitution for medications and in its new role, will also determine what biologics will be considered to be safely interchanged based on their guidelines. CPA supports efforts to safely make drug products and biologics affordable to both health plans and patients.

However, the CPA opposes the interchangeable biologic product substitution processes that require authorization, recordkeeping or reporting beyond our current standard of practice.

As you know, in 2011 CPA unsuccessfully fought legislation that carved out certain requirements for patients with epilepsy. We warned legislators at that time that it would set a precedence for other drugs or diseases to attempt a carve out to handle their product or drug class differently than what is the standard of practice for substitution. In 2013, we were successful in defeating a carve out for drugs treating blood disorders. Now we have biologics/biosimilars that are really not required to be processed any differently than we do any other prescription. To continue to dictate how and when we have to report different classes of drugs to various entities creates a systems nightmare.

The ultimate power to allow or disallow substitution rests with the prescriber. If a prescriber does not want a pharmacist to substitute a drug or a biologic, he/she simply has to state that when he writes the prescription. An example would be "brand medically necessary" or "No substitutions."

Additional reporting requirements by the pharmacies back to prescribers is counterproductive and costly to both the pharmacies and the patients. Specifically we are opposed to Section I of this proposed bill that requires pharmacies, within five business days following the dispensing of a biological product, to make an electronic entry of the specific product provided to the patient, including the name of the product and the manufacturer that is accessible to the prescriber. The legislation states that this can be done through:

- i. an interoperable electronic medical records system;
- ii. an electronic prescribing technology;
- iii. a pharmacy benefit management system; or iv. a pharmacy record

In Section (I) the proposed legislation then makes a presumption that if we do this by any means above it will serve as notification. This raises concerns for our members that the above meets the notification because we cannot guarantee what certain entities do with the information they receive.

In summary, we will continue to support legislation that provides alternative, less costly drug products for patients and we will work to find solutions so that we don't created unnecessary burdens for our pharmacists related to specific categories of medications.